DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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YD DIAGNOSTICS CORP.
YANG HO DONG
#821 SAMIL PLAZA 837-26
YEUKSAM-DONG, GANGNAM-GU,
(135-768), SEOUL KOREA

May 28, 2015

Re: K141874
Trade/Device Name: URiSCAN 2ACR Urine strips
URiSCAN Optima Urine analyzer
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: II
Product Code: JFY, JIR, KQO
Dated: April 8, 2015
Received: April 15, 2015

Dear Yang Ho Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141874

Device Name

URiSCAN Optima Urine analyzer and URiSCAN 2ACR Urine strips

Indications for Use *(Describe)*

The URiSCAN Optima urine chemistry test system consists of URiSCAN Optima Urine analyzer and URiSCAN 2ACR Urine strips. The intended use of the URiSCAN Optima Urine analyzer is to read the color change on the test pads found on the URiSCAN 2ACR Urine strips and to display and print the results.

The intended use of the URiSCAN 2ACR Urine strips is for the in vitro semi quantitative measurement of the following parameters;

Albumin
Creatinine
ACR (Albumin Creatinine Ratio)

These measurements are useful in the evaluation of renal, urinary and metabolic disorders. URiSCAN Optima urine chemistry test system is intended for prescription use only, in clinical laboratory and in point-of-care setting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: YD Diagnostics Corp.
#173 Seo-Ri, Yidong-Myun, Cheoin-Gu, Yongin-Si
Kyunggi-Do, 449-834, Korea

Contact Person: Ho Dong, Yang
Onbix Corporation
#821 Samil Plaza, 837-26 Yeuksam-dong
Gangnam-gu, Seoul, Korea
Tel: *82-2-566-3360 / Fax: *82-2-6280-3360
Email: onbix@naver.com

Date Summary Prepared: **Feb 05, 2015**

Device Name:

Trade Name(s):	URiSCAN Optima Urine analyzer and URiSCAN 2ACR Urine strips
Classification Name:	Urinalysis system
Panel:	Clinical chemistry
Product code:	JIR (protein or albumin) JFY (creatinine) KQO (Automated urinalysis system)

Predicate Device Information:
K091216 Clinitek Status (Siemens)

Device Description:
URiSCAN Optima – the semi-quantitative urine analyzer is used with the aim of helping examine patients in a professional setting through early detection of disease before they get a thorough checkup, by using chemical components contained in urine; and it is a device to measure the amounts of components in urine, including **albumin, creatinine and ACR (albumin creatinine ratio)**. The results appear on a liquid crystal display and can be printed on the analyzer's internal printer and transferred to a host computer, if desired.

Intended Use:
The URiSCAN Optima urine chemistry test system consists of URiSCAN Optima Urine analyzer and URiSCAN 2ACR Urine strips. The intended use of the URiSCAN Optima Urine analyzer is to read the color change on the test pads found on the URiSCAN 2ACR Urine strips and to display and print the results.

The intended use of the URiSCAN 2ACR Urine strips is for the in vitro measurement of the following parameters;

Albumin
Creatinine
ACR (Albumin Creatinine Ratio)

These measurements are useful in the evaluation of rena1, urinary and metabolic disorders. URiSCAN Optima urine chemistry test system is intended for prescription use only, in clinical laboratory and in point-of-care setting.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics.

No	Item	URiSCAN Optima	Clinitek Status (K091216)
1	Manufacturer	YD Diagnostics Corp	SIEMENS
2	Formation	Desk Top	Desk Top
3	Dimensions(W*D*H)	210*240*90 (mm)	170*272*158 (mm)
4	Weight	0.97 Kg	1.66 Kg
5	Voltage	Adapter, 12VDC 3.5A	110V AC, 45-65Hz
6	Storage/Operating Temperature	0 ~ +40℃ / +20 ~ 28+℃	+5 ~ +40℃
7	Storage/Operating Humidity	10 ~ 70%	20 ~ 80%
8	Throughput	36 tests/hour	50 tests/hour
9	Measuring Cycle	100 sec	70 sec
10	Result Memory	2,000 tests	200 tests
11	Interface	RS 232C, USB	RS 232 serial
12	Display	4.3" TFT LCD, Touch	Touch screen
13	Printer	Thermal printer	Thermal printer
14	Device image		
15	Analytes of device	Microalbumin Creatinine	Albumin, bilirubin, blood, creatinine, glucose, ketone, leukocytes, nitrite, pH, protein, protein-to-creatinine ration, albumin-to-creatinine ratio, specific gravity, urobilinogen, and human chorionic gonadotropin(hCG)
16	Test strip to be used with device	URiSCAN 2ACR Urine strips: microalbumin, creatinine and ACR	Clinitek microalbuin 2 : microalbumin, creatinine and ACR

Performance Characteristics (if/when applicable)

1. *Analytical performance*:
   a. *Precision/Reproducibility:*

Within-run and Within-day precisions were tested at three Clinical sites, using commercially MAS Urinalysis Control, Level 1 and Level 2. ***Within-run precision****:* These studies used three different analyzers URiSCAN Optima Urine Analyzer and three different lots of URiSCAN 2 ACR Urine strips. Testing was performed in 10 replicates for each control level (90 tests/analytes). Three operators each tested 10 test strips of each lot of strips on each analyzer (10 tests/analytes). ***Within-day precision***: These studies used three different analyzers URiSCAN Optima Urine Analyzer and three different lots of URiSCAN 2 ACR Urine strips. Three operators each tested each lot number of strips on each analyzer, one a day, for 10days.

Test Item	Level 1 -Negative Control	Level 2 -Positive Control
Microalbumin	≤10mg/L	80-≥150mg/L
Creatinine	10-50mg/dL	100 - ≥300mg/dL

Clinical site	Control	Site A	Site B	Site C
Microalbumin	Level 1	100%	100%	100%
	Level 2	100%	100%	100%
Creatinine	Level 1	100%	100%	100%
	Level 2	100%	100%	100%

   a. *Linearity/assay reportable range:*

This assay reports color block outputs of 0, 30, 80, 150 mg/L for albumin, and 10, 50, 100, 200, 300 mg/dL for creatinine

   b. *Traceability, Stability, Expected values (control, calibrator, or method):*

Traceability and Value assignment:

The control solutions were prepared in house by adding a commercially available stock of albumin and creatinine in buffered solutions. The traceability of internal control solutions is re-checked using a commercial calibrator set. The values for the standards of albumin and creatinine assigned through an internal procedure. The control target value assignments are summarized as below. Also, the calibrators have fixed values regardless of lot specific.

Standard material	Target value (of block)				
Albumin	10	30	80	150	-
(mg/L)	-	+	2+	3+	-
Creatinine	10	50	100	200	300
(mg/dl)	±	+	2+	3+	4+

Calibration:

The instrument performs a “self-test” and calibration each time it is turned on. Each time a test is run, the analyzer re-calibrates using a white plastic calibration bar located at the bottom of the analyzer optical system. Reflectance measurements from the bar must match the factory set calibration.

Stability:

Shelf-life and open-vial stability protocols and acceptance criteria were reviewed and found to be adequate for URiSCAN Optima analyzer and URiSCAN 2ACR Urine strips. The stability studies support the following manufacturer's claim. The Albumin/Creatinine strips are stable for 24 months in the closed package and for 3 months in opened package when stored at 15-30℃.

Shelf-life stability and opened vial protocol for controls were reviewed and found acceptable. The sponsor claims that the un-opened controls can be stored at 2-8℃ until the expiration date and the opened controls are stable for 24 months at 2-8℃.

c. Detection Limit:

Analytical sensitivities of the URiSCAN 2 ACR Urine strips on the URiSCAN Optima analyzer were evaluated by spiking negative pooled human urine with the Standard materials to obtain the desired concentrations. Urine samples for each analyte were prepared by spiking a negative urine pool with a minimum of 5 sample concentrations of each analyte across the measuring range for each test pad. Each concentration was tested 10 times on each analyzer using each strip type.

The cut-off values for each color block of albumin and creatinine are summarized below:

Analyte	Block output	Conc.	Block cut-off value	% positive results
Albumin	+	30 mg/L	20 mg/L	74.4%
	2+	80 mg/L	56 mg/L	74.7%
	3+	150 mg/L	116 mg/L	74.4%
Creatinine	+	50 mg/dL	30 mg/dL	56.7%
	2+	100 mg/dL	81 mg/dL	56.7%
	3+	200 mg/dL	181 mg/dL	56.7%
	4+	300 mg/dL	281 mg/dL	58.8%

Analyte	Concentrations tested	Percentage Agreement at Each Color Block			
		- (0 mg/L)	+ (30 mg/L)	2+ (80 mg/L)	3+ (150 mg/L)
Albumin	200 mg/L	0%	0%	0%	100%
	150 mg/L	0%	0%	0%	100%
	125 mg/L	0%	0%	0%	100%
	120 mg/L	0%	0%	0%	100%
	116 mg/L	0%	0%	25.6%	74.4%
	110 mg/L	0%	0%	70%	30%
	105 mg/L	0%	0%	100%	0%
	65 mg/L	0%	0%	100%	0%
	60 mg/L	0%	0%	100%	0%
	56 mg/L	0%	25.3%	74.7%	0%
	50 mg/L	0%	60%	40%	0%
	45 mg/L	0%	100%	0%	0%
	30 mg/L	0%	100%	0%	0%
	25 mg/L	0%	100%	0%	0%
	20 mg/L	25.6%	74.4%	0%	0%
	15 mg/L	70%	30%	0%	0%
	10 mg/L	100%	0%	0%	0%

Analyte	Concentrations tested	Percentage Agreement at Each Color Block (mg/dL)				
		± (10)	+ (50)	2+ (100)	3+ (200)	4+ (300)
Creatinine	350 mg/dL	0%	0%	0%	0%	100%
	300 mg/dL	0%	0%	0%	0%	100%
	290 mg/dL	0%	0%	0%	0%	100%
	285 mg/dL	0%	0%	0%	0%	100%
	281 mg/dL	0%	0%	0%	41.2%	58.8%
	275 mg/dL	0%	0%	0%	70%	30%
	270 mg/dL	0%	0%	0%	100%	0%
	190 mg/dL	0%	0%	0%	100%	0%
	185 mg/dL	0%	0%	0%	100%	0%
	181 mg/dL	0%	0%	43.3%	56.7%	0%
	175 mg/dL	0%	0%	80%	20%	0%
	170 mg/dL	0%	0%	100%	0%	0%
	90 mg/dL	0%	0%	100%	0%	0%
	85 mg/dL	0%	0%	100%	0%	0%
	81 mg/dL	0%	43.3%	56.7%	0%	0%
	75 mg/dL	0%	80%	20%	0%	0%
	70 mg/dL	0%	100%	0%	0%	0%
	40 mg/dL	0%	100%	0%	0%	0%
	35 mg/dL	0%	100%	0%	0%	0%
	30 mg/dL	43.3%	56.7%	0%	0%	0%
	25 mg/dL	80%	20%	0%	0%	0%
	20 mg/dL	100%	0%	0%	0%	0%

d. Analytical specificity:

We performed interference testing on substances that had previously shown false negative or false positive results for microalbumin and creatinine. We identified the concentration of the interfering substance that affects the albumin and creatinine pads. The concentrations of albumin used were 1+ (25 mg/L, 30 mg/L) and 3+ (150 mg/L) and the concentrations of creatinine used were 1+ (50 mg/dL) and 4+ (300 mg/dL). All interferences were tested 3 times using 3 lots of URiSCAN 2 ACR Urine strips and 3 serial numbers of URiSCAN Optima Urine analyzer. Also, we used 3 lots of URiSCAN 2 ACR Urine strips and 3 serial number of URiSCAN Optima Urine analyzer, depending on the concentration of the interfering substance.

The following table shows the substances which did interfere with one or more of the albumin and creatinine test pads. The results indicated are the lowest concentration of the interfering substance, based on the change of output of color-block:

Analyte	**Concentration of Substance at which Interference was observed**	**Change in Color Block Output**
Albumin	Calcium chloride ≥200 mg/dL, Fructose ≥80 mg/dL, Ascorbic acid ≥300 mg/dL, Citric acid ≥65 mg/dL, Sodium nitrite ≥8 mg/dL, Potassium chloride ≥1200 mg/dL, Sodium chloride ≥5000 mg/dL, Riboflavin ≥15 mg/dL, High specific gravity ≥1.050	-1
	Sodium bicarbonate ≥1350 mg/dL, Phenolphthalein ≥1050 mg/dL, Theophylline ≥85 mg/dL, Sodium acetate ≥250 mg/dL, Acetaminophen ≥40 mg/dL, High pH ≥pH 9, Bilirubin ≥4 mg/dL, Hemoglobin ≥5 mg/dL, Blood ≥300 mg/dL	+1
Creatinine	Glycine ≥430 mg/dL, Sodium bicarbonate ≥1200 mg/dL,	-1

	Sodium-2-mercaptoethene ≥510 mg/dL, High pH ≥pH 9	
	Calcium chloride ≥220 mg/dL, Sodium chloride ≥5200 mg/dL, Albumin ≥890 mg/dL, Theophylline ≥90 mg/dL	+1

The test result of interfering substances was summarized as follows with respect to the concentration of albumin and creatinine.

Interferences (mg/dL)	Conc.Tested (mg/dL)	Albumin (mg/L)			Creatinine (mg/dL)	
		1+ (25)	1+ (30)	3+ (150)	1+ (50)	4+ (300)
Calcium chloride	270	FN (200)	FN (200)	FN (200)	FP (220)	No
Glycine	450	No	No	No	FN (430)	FN (430)
Fructose	100	FN (80)	FN (80)	No	No	No
Ascorbic acid	500	FN (300)	FN (300)	FN 300	No	No
Citric acid	75	FN (65)	FN (65)	No	No	No
Sodium nitrite	10	FN 8	FN 8	FN 8	No	No
Potassium chloride	1500	FN (1200)	FN (1200)	FN (1200)	No	No
Sodium chloride	5500	FN (5000)	FN (5000)	FN (5000)	FP (5200)	No
Sodium bicarbonate	1500	FP (1350)	FP (1350)	No	No	FN (1200)
Albumin	1000	N/A	N/A	N/A	FP (890)	No
Sodium-2-mercaptoehene	530	No	No	No	FN (510)	FN (510)
Phenolphthalein	1200	FP (1050)	FP (1050)	No	No	No
Theophylline	100	FP (85)	FP (85)	No	FP 90	No
Riboflavin	20	FN (15)	FN (15)	FN (15)	No	No
Sodium acetate	280	FP (250)	FP (250)	No	No	No
Acetaminophen	50	FP (40)	FP (40)	No	No	No
High pH	pH 9	FP (pH 9)	FP (pH 9)	No	FN (pH 9)	FN (pH 9)
Bilirubin	4	FP 4	FP 4	No	No	No
Hemoglobin	5	FP 5	FP 5	No	No	No
Blood	300	FP 300	FP 300	No	No	No
High Specific gravity	1.050	FN 1.050	FN 1.050	FN 1.050	FP 1.050	No

FN, False Negative; FP, False positive

"No" means that the no interference was observed at these interference and analyte levels.

"N/A" means that the not applicable.

Specific Gravity and pH studies:

Interference tests for specific gravity were performed using the URiSCAN 2 ACR Urine strips and the URiSCAN Optima urine analyzer. The evaluation for specific gravity used 11 samples (specific gravity 1.000, 1.050, 1.010, 1.015, 1.020, 1.025, 1.030, 1.035, 1.040, 1.045, 1.050). All tests were performed in 3 replicates per each sample. The concentrations of albumin used were 1+ (30 mg/L) and 3+ (150 mg/L). In this study, we added 25mg/L albumin. The reason is that this is the lowest concentration of albumin that identified false negative or false positive interpretations for specific gravity. The concentrations of creatinine used were 1+ (50 mg/dL) and 4+ (300 mg/dL). Also, we performed the tests using 3 lots of URiSCAN 2 ACR Urine

strips and 3 serial numbers of the URiSCAN Optima Urine analyzer. The methology references are from “Interference testing in clinical chemistry; Approved Guideline”; CLSI EP7-A. The Albumin reagent pad, under the following conditions, showed false negative results and the creatinine reagent pad, under the following conditions, showed false positive results: high specific gravity at 1.050.

Temperature and Humidity studies:

We have performed the real time stability study to demonstrate the shelf-life of URiSCAN 2 ACR Urine strips' storage at temperature (-2~30℃) and humidity (10, 30, 60, 90%). Samples were created by spiking known concentrations of each standard material or by serial dilution of a high concentration with negative urine. Testing was done with urine sample concentrations at 3 level of albumin (30, 80, 150 mg/L) and 6 levels of creatinine (10, 50, 100, 200, 300 mg/dL). Testing was done on three instruments using three different lot numbers of test strips, 1 test per strip lot on each instrument at each level. We kept the reagent strips (3 Lots) checked for 30 months. The recommended storage temperature range for the URiSCAN 2 ACR Urine strip is between 15~30℃ and a relative humidity of less than 60%. Also, opened vial stability claim of the strip is that the strips are stable at least 3 months. Un-opened vial stability claim of the strips is stable for 24 months from the date of manufacture. Stability data support the following manufacturer claim: The strip can be stored at room temperature and humidity, closed package to 24 months, opened package to at least 3 months from the manufacture date.

e. *Assay cut-off:*

See detection limits above.

2. Comparison studies:

a. Method comparison with predicate device:

The evaluation followed “Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002) NCCLS, EP9A. Comparison studies were performed at three different POC sites (3 site) and the 351 samples were tested the 3 sites, 157 samples at the first, 99 samples at second and 95 samples from the third. Fresh urine specimens collect in a clean, dry container at the site.

A total of 351 random urine specimens were collected. Each specimen was tested by URiSCAN Optima Urine Analyzer with URiSCAN 2ACR Urine strips and by Clinitek Status with Clinitek Microalbumin 2 reagent strips. Percent agreement with Clinitek Microalbumin in microalbumin test: 95.7%, Positive Agreement: 100.0%, Negative Agreement: 100.0%. Percent agreement with Clinitek Microalbumin in creatinine test: 96.6%. Percent agreement with Clinitek Microalbumin in ACR (albumin:creatinine ratio) test: 98%, Positive Agreement: 97.8%, Negative Agreement: 98.3%. The results are listed in the table below.

The summary comparative results with UriScan Optima and Predicate device.

Microalbumin (n=351)		Predicate device (mg/L)			
		10	30	80	150
URiSCAN Optima Urine Analyzer (mg/L)	3+			7	66
	2+		6	87	1
	1+		92	1	
	Neg.	91			

Total	91	98	95	67
Exact agreement (%)	100.0	93.9	91.6	98.5
Within One Block (%)	100.0	100.0	100.0	100.0

Creatinine (n=351)		Predicate device (mg/dL)				
		10	50	100	200	300
URiSCAN Optima Urine Analyzer (mg/dL)	4+				2	38
	3+			1	63	2
	2+		1	87	1	
	1+	3	94	2		
	+-	57				
Total		60	95	90	66	40
Exact agreement (%)		95.0	98.9	96.7	95.5	95.0
Within One Block (%)		100.0	100.0	100.0	100.0	100.0

ACR (n=351)		Predicate device (mg/g)		
		<30	30-300	>300
URiSCAN Optima Urine Analyzer (mg/g)	>300			57
	30-300	2	169	1
	<30	118	4	
Total		120	173	58
Exact agreement (%)		98.3	97.7	98.3
Within One Block (%)		100.0	100.0	100.0

b. Matrix comparison:
Not applicable

3. Expected values/Reference range

The expected valuesare included in the labeling and are taken from literature reference. Albumin is normally present in urine at concentrations of less than 20 mg/L.[2] Microalbuminuria is defined as an albumin excretion rate of 30 ~ 299 mg/24 hours.[3),4)] Urinary albumin excretions can be temporarily elevated by exercise, urinary tract infections, and acute illness with fever. Creatinine is normally present in urine at concentrations of 10 to 300 mg/dL (0.9 ~ 26.5 mmol/L). Albumin to Creatinine Ratio: Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine (3.4 mg albumin /mmol creatinine). Microalbuminuria is indicated at a ratio result of 30 ~ 300 mg/g (3.4 ~ 33.9 mg/mmol) and clinical albuminuria at a ratio result of > 300 mg/g (> 33.9 mg/mmol).[1)]

1) Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.
2) Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: Saunders; 1999; pp. 483-484.
3) Mangili, R. *et al*.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1(Insulin Dependent) Diabetic Patients without Penal Failure in Italy – Validation of Screening.
4) American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008.

4. Clinical studies:

Non-Clinical study performance was conducted on the URiSCAN Optima Urine analyzer using the URiSCAN 2ACR Urine strips.

5. Conclusion

Based on the information provided in this summary we conclude that URiSCAN Optima urinalysis system is safe and effective and substantially equivalent to the predicate device K091216.